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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,659	08/10/2001	Einar Stefansson	032904-001	4462

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EXAMINER	
FAY, ZOHREH A	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,659	STEFANSSON, EINAR	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,12-26,31 and 37-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 12-26, 31 and 37-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 6, 12-26, 31 and 37-51 are presented for examination.

The amendments and remarks filed on August 23, 2004 have been received and entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 12-26, 31 and 37-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain carbonic anhydrase inhibitors for slowing the progression of diabetic retinopathy, does not reasonably provide enablement for all carbonic anhydrase inhibitors being used for slowing the progression of diabetic retinopathy in a diabetic not suffering from diabetic retinopathy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to the use of a carbonic anhydrase inhibitor for slowing the progression of diabetic retinopathy in a diabetic not suffering from diabetic retinopathy.

2) The state of the prior art:

The prior art does not recognize that all carbonic anhydrase inhibitors have the same function. Applicant on page 5 of the specification admits that not all carbonic anhydrase inhibitors have the same therapeutic activity. Applicant admits that some of carbonic anhydrase inhibitors have been used as diuretics for treatment of congestive heart failure or in the treatment of allergies.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are very broad and encompass the use of any carbonic anhydrase inhibitor for slowing the progression of diabetic retinopathy in a diabetic not suffering from diabetic.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for slowing the progression of diabetic retinopathy using one carbonic anhydrase inhibitor, dorzolamide. However, the specification provides no guidance, to enable one of ordinary skilled in the art to use the invention commensurate in scope with the claims. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: " It is well settled that in cases involving chemical and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by enumeration of a sufficient number of the members of a group or by other appropriate

language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired results". Applicant's specification does not set forth a representative number of examples of the carbonic anhydrase inhibitors for slowing the progression of diabetic retinopathy.

7) The presence or absence of working examples:

The examples in applicant's specification are drawn to the use of one carbonic anhydrase inhibitor, dorzolamide for slowing the progression of diabetic retinopathy.

8) The quantity of experimentation necessary:

Since compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all carbonic anhydrase inhibitors which are capable of slowing the progression of diabetic retinopathy.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 12-26, 31 and 37-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 12-26, 31 and 37-51 are indefinite as to the expression "slowing the progression of diabetic retinopathy in a diabetic not suffering from diabetes". The term "

slowing the progression of diabetic retinopathy" indicates that the person already has had diabetic retinopathy.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 12-26, 31 and 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/44603, Doshi et al. The WO Patent on page 2 lines 1-10 teaches that of the two types cystoid macular edema the one with vascular leakage comprises diabetic retinopathy. See line 7. The above reference also teaches the use of carbonic anhydrase inhibitors in combination with a hypotensive agent for the treatment of prevention of macular edema or any ocular disorder with the etiology inadequate vascular perfusion. See page 6 lines 20-24 and page 7, line1. Doshi teaches the use of a carbonic anhydrase inhibitor for the treatment of macular edema. See column 2, lines 28-37. The primary reference differs from the claimed invention in the use of a carbonic anhydarse inhibitor per se for the treatment of diabetic retinopathy. It would have been obvious to a person skilled in the art to use a carbonic anhydrase inhibitor for the treatment of diabetic retinopathy, considering that macular edema covers diabetic retinopathy as well.

One skilled in the art would have been motivated to combine the teachings of the above references, since one makes clear that macular edema covers diabetic retinopathy as well, and the other relates to the use of carbonic anhydrase inhibitors for

the treatment of macular edema. To use a composition being used for the treatment and prevention of diabetic retinopathy and use it for slowing the progression of diabetic retinopathy would have been obvious to a person skilled in the art. The substitution of one carbonic anhydrase inhibitor for another is considered to be within the skill of artisan in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 6, 12-26, 31 and 37-51 are properly rejected under 35 U.S.C. 103.

The amendments of august 23, 2004 necessitate the new ground of rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F